

K962846

OCT 23 1996

**Section 510(k)
Premarket Notification**

Summary of Safety and Effectiveness Information

Regulatory Authority: Safe Medical Devices Act of 1990, 21 CFR 807.92

Device Trade Name: EZ-Fix™ Compression Hip/Supracondylar Screw (CHS) System

Common Name: Compression Hip/Supracondylar Screw

Registration Number: 888.3030

Classification Name: Appliance, Fixation, Nail/Blade/Plate Combination, Multiple Component, Metal Composite

Product Code: 87LXT

Establishment Name & Registration Number:

Name: Biodynamic Technologies, Inc.
East Newport Center Drive
Deerfield Beach, Florida 33442
(305) 421-3166 (305) 570-6368 FAX

Number: 1035157

Classification:

Device Class: Class II

Classification Panel: Orthopedic

Contact Person:

Danny Hodgeman
Biodynamic Technologies, Inc.
East Newport Center Drive
Deerfield Beach, Florida 33442
(305) 421-3166 (305) 570-6368 FAX

Special Controls:

Not applicable to this device.

Device Description:

The EZ-Fix™ Compression Hip/Supracondylar Screw system is manufactured from titanium (6Al-4V ELI) per ASTM F136. It is light weight. The barrel and plate (keyed and non-keyed) are one solid piece (non-modular), is available in 95°, 130°, 135°, 140°, 145° and 150° angles and is manufactured and tested per ASTM specifications F787 and F384 respectively. The bone screw hole pattern is offset and the most proximal hole accepts a large diameter cannulated screw. The plates shall be available in 3 hole, 4 hole, 5 hole, 6 hole, 8 hole, 10 hole, 12 hole and 14 hole lengths. The bone screws are self-tapping and the lag screws are available in 50-150 mm (5 mm increments) lengths. A compression screw threads into the lag screw to allow for optimal compression of the lag screw into the barrel during implantation.

Substantially Equivalent Devices:

1. **Alphatec Modular Hip Screw System**
See Appendix III for promotional materials for the comparison device.
2. **Ace Captured Hip Screw System**
See Appendix III for promotional materials for the comparison device.
3. **Richards Classic and AMBI Compression Hip Screw Systems**
See Appendix III for promotional materials for the comparison device.
4. **Howmedica ALTA Modular Hip Screw System**
See Appendix III for promotional materials for the comparison device.
5. **Zimmer Free-Lock Compression Hip Fixation System**
See Appendix III for promotional materials for the comparison device.
6. **Zimmer Versa-Fx Femoral Fixation System**
See Appendix III for promotional materials for the comparison device.

Comparison to Predicate Device:

The EZ-Fix™ Compression Hip Screw System is substantially equivalent to the Alphatec, Ace, Richards, Howmedica and Zimmer compression hip screw systems in that they are combination lag screw, bone screws, compression screw and plate fixation devices with indicated for single use to stabilize intracapsular fractures of the neck of the femur; class I, II, III, and IV trochanteric and subtrocjanteric fractures with appropriate additional postoperative precautions against weight-bearing and against more than sedentary activity; supracondylar fractures and distal femoral fractures using a 95° barrel angle, making it substantially equivalent to Alphatec, Richards, Howmedica and Zimmer. The EZ-Fix™ CHS is contraindicated for attachment or fixation to the posterior elements (pedicles) of the cervical, thoracic, or lumbar spine. It is fabricated and tested per ASTM standards.

The EZ-Fix™ CHS is substantially equivalent to the Alphatec, Richards, Howmedica and Zimmer systems in that it include self-tapping bone screws.

The EZ-Fix™ CHS is substantially equivalent to Alphatec, Richards' Classic, Howmedica and Zimmer in that it accepts a large cannulated screw in the most proximal plate hole.

The EZ-Fix™ CHS is substantially equivalent to Alphatec, Ace, and Howmedica in that it is fabricated from titanium alloy (Ti-6Al-4V ELI). It is equivalent to the Richards, and Zimmer systems in that the barrel and plate are non-modular (solid) in design and the screw hole pattern along the length of the plate is offset.

The EZ-Fix™ CHS is substantially equivalent to Alphatec, Richards' AMBI, Howmedica, and Zimmer Free-Lock being available keyed or keyless with regard to the barrel and lag screw design.

The EZ-Fix™ CHS is substantially equivalent to Alphatec, Richards, Howmedica, and Zimmer Versa Fx in that the barrel plate angles include 95°, 130°, 135°, 140°, 145°, and 150°. Like Alphatec, the EZ-Fix™ lag screws are available in lengths ranging from 50 mm to 150 mm.

Packaging:

Sterile

- The EZ-Fix™ Compression Hip Screw devices may be supplied sterile.
- The devices are packaged individually in a blister package consisting of a thermoformed inner tray that contains the EZ-Fix™ Rod. This tray is protected by an outer thermoformed tray that is sealed by TYVEK CR-27. The outer TYVEK cover is labeled and has affixed to it the Patient Chart Labels. Both the inner and outer trays when sealed with the TYVEK cover are enclosed in a box that is sealed and indicates the sterility of the contents. Packaging material consists of .025 BT/CTD PETG, WEB#1:CTD 1073B TYVEK CR-27.

Non-Sterile

- The EZ-Fix™ Compression Hip Screw devices and all instrumentation may be supplied non-sterile.
- Steam autoclavable sterilization trays have been designed to contain the EZ-Fix™ CHS System and maintain adequate separation of the implants and instruments.

Sterilization / Re-sterilization:

Sterile

- The EZ-Fix™ Compression Hip Screw devices may be supplied sterile.
- Sterilization is achieved by means of gamma radiation.
- Sterilization complies with ANSI/AAMI/ISO 11137-1994 practices.
- 10% of each production lot of EZ-Fix™ devices are tested (6% for bacteriostasis - fungistasis studies and 4% for bioburden recovery determination)
- The devices are packaged individually in a blister package consisting of a thermoformed inner tray that contains the EZ-Fix™ Rod. This tray is protected by an outer thermoformed tray that is sealed by TYVEK CR-27. The outer TYVEK cover is labeled and has affixed to it the Patient Chart Labels. Both the inner and outer trays when sealed with the TYVEK cover are enclosed in a box that is sealed and indicates the sterility of the contents. Packaging material consists of .025 BT/CTD PETG, WEB#1:CTD 1073B TYVEK CR-27.
- The radiation dose is based on the ANSI/AAMI/ISO 11137.1994 dose setting.
- Sterilization Assurance Level (SAL) is 10⁻⁶.

- Sterilization process used is Cobalt 60.
- The EZ-Fix™ devices are non-pyrogenic. Pyrogenicity testing of the devices to determine level of endotoxin performed using LAL (Limulus Amebocyte Lysate) method.

Non-Sterile

- The EZ-Fix™ Compression Hip Screw devices and all instrumentation may be supplied non-sterile.
- Steam autoclavable sterilization trays have been designed to contain the EZ-Fix™ CHS System and maintain adequate separation of the implants and instruments.
- Sterilization cycles should be followed appropriately to achieve a 10⁻⁶ sterility assurance level (SAL).
- See Appendix I for Sterilization Procedure
- The EZ-Fix™ devices are non-pyrogenic. Pyrogenicity testing of the devices to determine level of endotoxin performed using LAL (Limulus Amebocyte Lysate) method.

Testing:

The EZ-Fix™ Compression Hip/Supracondylar Screw (CHS) system has been tested by the University of Miami Biomechanics Laboratory at Mount Sinai in Miami Beach, Florida, based upon ASTM test standards for metallic nail-plate appliances (F384). Test results proved the device to be of sound design.

Equivalence :

These test values are comparable to those obtained from the referenced equivalent.

Conclusion:

Based on the materials, intended uses, design, testing, and manufacturing, the EZ Fix™ Compression Hip/Supracondylar Screw System is equivalent to the referenced legally marketed comparison devices. The feature comparison chart below graphically demonstrates equivalence.

Comparison Table:

EZ-Fix™ CHS	Alphatec MHS	Ace® CHS	Richards AMBI / Classic	Howmedica Alta	Zimmer Free Lock / Versa
<u>Materials</u>					
Titanium Alloy	Titanium Alloy	Titanium Alloy	Stainless Steel Stainless Steel	Titanium Alloy	Stainless Steel Stainless Steel
<u>Keyed / Keyless</u>					
Both	Both	Keyless	Keyable Keyed	Both	Keyable Keyed
<u>Plate Design</u>					
Solid	Modular	Modular	Solid Solid	Modular	Solid Solid